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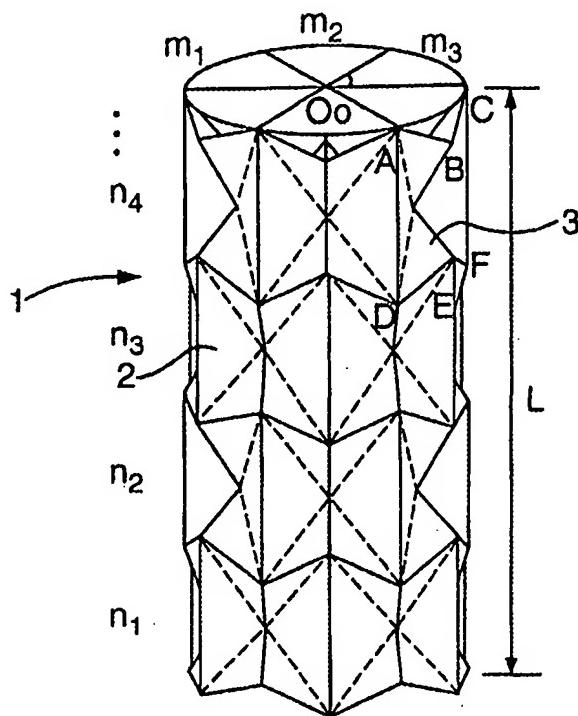
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(54) Title: DEPLOYABLE STENT



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(57) Abstract: A stent 1 comprising a sheet 2 of biocompatible material arranged as a tube and having a pattern of folds allowing the stent to be collapsed for deployment. The pattern of folds comprises a unit cell repeated over the sheet 2. A variety of different unit cells 3 are described. The pattern of folds may progress helically around the tube which assists in implantation by synchronising deployment. The stent 1 prevents restenosis because it is formed of a continuous sheet 2, and allows slippage to be minimised.

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DEPLOYABLE STENT

The present invention relates to a stent. The present provides a novel structure for a stent, and also relates to the manufacture and use of the stent.

A stent is a medical device designed to open up a blocked lumen at a site in
5 the human (or even animal) body, for instance a coronary artery, aorta or the oesophagus etc. The occlusion might be caused for instance by a disease such as stenosis or by cancer. Stents preferably have a flexible structure allowing them to be collapsed to reduce their outer dimensions. This is to facilitate the passage of the stent into the site in the body where the stent is expanded for deployment. Typical
10 uses of a stent are to open blocked coronary arteries and large veins, to treat obstructions to breathing in the trachea and bronchus, to allow the passage of urine in the prostate and, more recently, to palliate cancer stenosis in the oesophagus. Stent therapy is now widely accepted for interventional treatment not only in the vascular system, but also the gastrointestinal, biliary and urinary systems. Stent techniques
15 have come to be regarded as simply, safe and effective in comparison to other surgical or non-surgical treatments.

Known stents have one of five basic constructions that is tubular, coil, ring, multi-design and mesh structures. Tubular stents are rigid. The other types of known structures are collapsible and typically comprise an open tubular structure of
20 structural elements which may be collapsed to facilitate deployment. The various known structures have different features and advantages, for example a high expansion rate, a high strength, good flexibility and/or good tractability. Whilst some structures provide different combinations of these advantages, an ideal stent sharing all these advantages has yet to be realised.

25 One of the major problems with known stents is restenosis occurring after implantation. This is a particular problem for mesh stents and other open structures as tissues grow through the stent and block the lumen again and is a particular problem in oesophageal applications. Some reports suggest that restenosis is due to cell damage occurring during deployment at the blocked site as the stent pushes
30 against the cell wall. The amount of such damage is dependent on the stent

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configuration. After significant tissue growth through a stent, the stent cannot be retrieved. Thus it may be necessary to implant further stents after a first stent becomes blocked in order to reopen the blockage. As this involves stents being implanted inside one another, there is a limit to the number of stents which can be
5 implanted at one location.

To overcome this problem, covered stents have been developed. Covered stents were developed by attaching a tubular flexible cover, for example of polyester, attached around the outside of a wire mesh stent structure. The use of such a cover around a wire mesh stent is an effective way to prevent restenosis. However, the
10 common problems of covered stents include rupture of the cover and, when used in the oesophagus, for example, bolus obstruction, tumour in-growth, gastro-oesophageal reflux, migration/slippage, and difficulties in delivery especially for high oesophageal malignancies and angulated cardio-oesophageal lesions. The risk of slippage and hence migration of the stent is a particular problem. Such covered
15 stents still rely, for example, on a mesh frame for collapse and expansion during deployment, but there has been very little investigation of the integrated expanding mechanism when the stent is covered.

As a result of the problems described above for both covered and uncovered stents re-intervention is often required. As a result many patients have sub-optimal
20 response to this type of treatment.

Current expandable stents are expensive to manufacture due to their complicated structures which are labourious to form. The high cost has reduced their widespread use. Particularly for the oesophagus, doctors often opt for cheaper, semi-rigid plastic tubular stents even though they carry a higher risk of oesophagus
25 perforation than the expandable stents.

The present invention is intended to provide a stent which avoids at least some of the problems discussed above.

According to the present invention, there is provided a stent comprising a biocompatible sheet arranged as a tube folded with a pattern of folds allowing the
30 stent to be collapsed for deployment.

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Such a structure for a stent provides numerous advantages. As the stent is formed from a sheet, restenosis is prevented. Furthermore, the pattern of folds allows the stent to be collapsed for deployment facilitating delivery to the blocked site in the body. The pattern of folds may allow the tube to be collapsed both radially 5 and longitudinally of the tube. Alternatively, the pattern of folds may only allow the tube to be collapsed radially. Longitudinal collapse is advantageous where the blocked site is particularly inaccessible. On the other hand, in many uses the medical practitioner finds it more convenient if there is no longitudinal collapse in order to judge the length of the deployed stent prior to deployment. For such uses, it is 10 preferred to use a pattern of folds which has a reduced or zero longitudinal collapse.

The stent may also reduce slippage as compared to a known covered stent. Firstly, the folds may provide an uneven outer surface which reduces slippage. Secondly, the outer surface may be provided with a high degree of friction, for example by selection of the biocompatible material of the stent or by roughening the 15 outer surface.

The use of a pattern of folds to collapse the stent allows it to be packaged compactly and to have good flexibility for ease of delivery to the blocked site. The structure can be simple in structural form and is hingeless which increases reliability. The design of the stent is generic, so it can be adapted for use at different anatomical 20 sites. For example, by varying the diameter, length and/or bifurcation the stent may be collapsed for retrieval at a later date after implantation.

As the stent may be manufactured simply by folding a sheet, it is relatively simple to manufacture. This will minimise costs and it is anticipated that costs might be kept below many known expandable stents.

25 The stent is particularly useful for use in the oesophagus, where restenosis is a particular problem, or as a stent graft in the aorta. However, the stent may be used at any site in the body by appropriate sizing of the stent.

Many different patterns of folds are possible. Desirably, for ease of the design and manufacture wherein the pattern of folds comprises a unit cell repeated 30 over at least a portion of the sheet, or the entire sheet.

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In the preferred pattern of folds, wherein the unit cell comprises: an outer circumferential edge of hill folds comprising a pair of longitudinal edge folds extending along the tube and transverse edge folds extending around the tube; a central longitudinal fold extending along the tube between the transverse edge folds;

5 and angular folds extending from each intersection of a longitudinal edge fold with a transverse edge fold to the central longitudinal fold. Many variations within this pattern are possible.

The choice of pattern may be selected to balance the ease of deployment, which generally improves as the degree of overlap in the folded pattern decreases,

10 with the compactness of the stent when collapsed, which generally improves as the degree of overlap in the folded structure increases.

A particularly advantageous pattern is one which progresses helically around the tube. For example, the pattern of folds may include uninterrupted lines of folds progressing helically around the tube. Alternatively, the pattern of folds may

15 comprise at least one row of unit cells progressing helically around the tube.

Such a helical pattern provides a number of advantages. Firstly, it can be folded more compactly in the longitudinal direction, because of the twist in the pattern, in comparison with a stent having a pattern of folds which does not progress helically.

20 Secondly, the stent with a helical pattern may be deployed more easily, because the collapse and expansion of the stent is synchronised. That is to say, the helical pattern causes the forces during collapse and expansion to be transferred along the tube. This may be envisaged as being caused by the force being transferred along uninterrupted lines of folds progressing helically around the tube.

25 Consequently, collapse and expansion of the tube may be induced by the simple expedient of twisting the tube. As such a twist is easy to apply, this greatly improves the ease of deployment.

Thirdly, the helical pattern holds the stent in its expanded configuration.

In order that the present invention may be better understood, the following

30 description of embodiments of the present invention is given by way of non-

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limitative example with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of a stent using one of the folding patterns in accordance with the present invention;

Fig. 2 is a diagram of a unit cell of a pattern of folds with the sheet in its 5 unfolded state;

Fig. 3 is a diagram of the sheet with unit cell of Fig. 2 developed to form the overall pattern of folds with the sheet in its unfolded state;

Fig. 4 is a progression of end views of the stent of Fig. 1 during expansion and contraction;

10 Figs. 5, 7, 12, 13, 15-19, 21-24, 26-31, 33 and 34 are diagrams of unit cells with alternative patterns of folds with the sheet in its unfolded state;

Figs. 6, 8, 14, 20, 25, 32, and 35-42 are diagrams of sheets with alternative patterns of folds with the sheet in its unfolded state;

15 Figs. 9 to 11 are graphs of the change in dimensions of a stent against the number of unit cells in the pattern of folds; and

Fig. 43 is a view of a portion of a sheet of the stent showing an aperture at a node where folds intersect.

20 A stent 1 in accordance with the present invention is illustrated in Fig. 1. The stent 1 comprises a biocompatible sheet 2. The sheet 2 is arranged as a tube with a pattern of folds which allow the stent to be collapsed for deployment.

The pattern of folds comprises a unit cell 3 which is repeated over the entire area of the sheet 2. The pattern of folds is illustrated more clearly in Figs. 2 and 3 which are views of, respectively, the unit cell 3 and the unit cells developed over the sheet 2 in the unfolded state, notionally "unwrapped" from its tubular form, the lines 25 a-a and b-b being the same line longitudinally along the tube. The unit cells 3 are in rows repeating around a direction perpendicular to the longitudinal axis of the tube.

In Figs. 2 and 3, and indeed the further figures illustrating patterns of folds, the lines are fold lines where the sheet 2 is folded. Between the folds, the sheet 2 is flat or planar. Continuous and dashed lines indicate folds of first and second 30 opposite types. The two types are valley and hill folds. Hill folds are folds which

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form a peak when viewed from the outer side of the tube. Valley folds are folds which form a valley when viewed from the outer side of the tube. In the following description, it will be assumed that the folds of the first type are hill folds and the folds of the second type are valley folds.

5 In general, the two types of fold are reversible in any given pattern, that is replacing all hill folds with valley folds and replacing all valley folds with hill folds. However, some patterns when reversed cause the tube to lock and hence do not allow the tube to be collapsed or expanded. The present invention contemplates the alternative that the folds of the first type are valley folds and the folds of the second
10 type are hill folds, except when this causes locking of the structure.

For convenience, the pattern of folds illustrated in Figs. 1 to 3 is referred to as Pattern 1.

The unit cell 3 comprises the following folds.

Unit cell 3 has an outer circumferential edge of hill folds. In particular, these
15 are a pair of longitudinal edge folds 4 extending along the tube parallel to one another and transverse edge folds 5 extending around the tube.

The unit cell 3 further comprises a central longitudinal fold 6 extending along the tube between the transverse edge folds 5.

Lastly, the unit cell 3 has four angular folds 7 each extending from a
20 respective intersection A, C, D or F of a longitudinal edge fold 4 with a transverse edge fold 5 to the central longitudinal fold 6. All four angular edge folds 7 intersect the central longitudinal fold 6 at the same position O. The length l of each transverse edge fold 5, that is from the intersection (e.g. at A) with a longitudinal edge fold 4 to a central intersection (e.g. at B) with the central longitudinal fold 6, is equal to the
25 length of the portion of the central longitudinal fold 6 from the central intersection (e.g. at B) with the transverse edge fold 5 to the intersection (e.g. at O) with an angular fold 7. Therefore, the triangle AOB and equivalent triangles within the unit cells 3 are isosceles triangles. The angle α (e.g. angle OAB) between a transverse edge fold 5 and an angular fold 7 is 45° .

30 The unit cell 3 is symmetrical about the central longitudinal fold 6 and about

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an imaginary line extending around the tube perpendicular to the central longitudinal fold 6 and intersecting the central longitudinal fold 6 at O.

The angular folds 7 are valley folds and the central longitudinal fold 6 is a hill fold. Accordingly, the unit cell 3 is folded as illustrated in perspective view in Fig. 1
5 where the intersections A to F of the various fold lines from Fig. 2 are indicated for one of the unit cells 3.

The unit cell 3 is repeated as illustrated in Fig. 3. In particular, the unit cells 3 are arranged in rows 8 labelled n_1, n_2, \dots , the rows repeating along the tube. The unit cells 3 of adjacent rows are offset, as illustrated by the unit cells 3 illustrated in
10 bold outline in Fig. 3, that is with the longitudinal edge folds 4 of each row 8 meeting the central longitudinal folds 6 of the adjacent rows 8. The number n of rows 8 labelled n_1, n_2, \dots in Figs. 1 and 3 and the number m of unit cells 3 within each row around the tube labelled m_1, m_2, \dots in Figs. 1 and 3 can be freely varied. Similarly,
the absolute dimensions of the sheet 2 and the unit cell 3 can be freely varied.

15 One of the interesting properties of Pattern 1 is that it causes the stent 1 to collapse and expand both longitudinally and radially. That is both the length of the tube and the radius of the tube increase during expansion and decrease during collapse. This property provides the advantage that the folded stent 1 can be packaged compactly. This makes the stent 1 easier to deliver through narrow
20 passages of the body and facilitates deployment at a blocked site where it can be expanded.

Fig. 4 is a progression of end views of the stent 1 during its expansion and contraction. As can be seen from Fig. 4, the central part of the unit cell 3 at the intersection (at O) of the angular fold 7 with the central longitudinal fold 6 moves
25 inwardly and outwardly, causing a change in the radius of the stent 1 during deployment. This also causes a reduction in the distance between the intersections (at B and E) between the central longitudinal fold 6 and the transverse edge folds 5, which causes a change in the axial length L of the stent 1.

Further possible patterns of folds will now be described. The further patterns
30 of folds are variations on Pattern 1 shown in Figs. 1 to 3. For clarity and for brevity,

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the further patterns will all be described by explaining the variations from Pattern 1 without repeating the common features. The same reference numerals as for Pattern 1 will be used to denote the sheet 2, the unit cell 3, the equivalent folds 4 to 7 and the rows 8.

- 5 Pattern 2 is illustrated in Figs. 5 and 6. Fig. 5 is a diagram of the unit cell 3 and Fig. 6 is a diagram of the sheet with the unit cell 3 developed across the sheet 2. Pattern 2 is similar to Pattern 1 except that the angle α (e.g. angle OAB) between each transverse edge fold 5 and angular fold 7 is less than 45° , so the unit cell 3 is no longer rectangular.
- 10 Pattern 3 is illustrated in Figs. 7 and 8. Fig. 7 is a diagram of the unit cell 3 and Fig. 8 is a diagram of the sheet 2 with the unit cell 3 developed across the sheet 2.

15 Pattern 3 varies from Pattern 1 in that the angle α (e.g. angle OAB) between each transverse edge fold 5 and in respect of angular fold 7 is greater than 45° and less than or equal to 60° . As a result the shape of the unit shape 3 becomes a polygon. The angle α should be equal to or less than 60° to allow folding of the sheet 2.

20 Pattern 3 also varies from Pattern 1 in that the angular folds 7 do not all intersect the central longitudinal fold 6 at the same position. Instead, for each pair of angular folds 7 at opposite longitudinal ends of the unit cell 3, the pair of angular folds 7 intersect the central longitudinal folds 6 at the same position, but the pairs of angular folds 7 intersect the central longitudinal fold 6 at separated positions O and X. Between these separated positions O and X, the central longitudinal fold 6 is a valley fold. However, the portions of the central longitudinal fold 6 extending from a central intersection (at B or E) with a respective one of the transverse edge folds 5 to a respective intersection (at O or X) with the angular folds 7 remain as hill folds. The separation between the intersections (at O and X) of each pair of angular folds 7 and the central longitudinal fold 6 may be freely varied. This separation may be reduced to zero (as in Patterns 1 and 2), but the longitudinal length of the unit cell 3, 30 or more particularly the length of the central longitudinal fold 6, may not be further

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reduced or else folding is prevented.

To understand and compare the folding of Patterns 1 to 3, the geometric properties of Patterns 1 to 3 have been analysed as follows. The analysis is based on Pattern 2 with the angle α as 30° and on Pattern 3 with the angle α as 60° .

5 Firstly, the ratio R^* of the outer radius of stent 1 (ie the distance from O_o to A or B) in its fully folded configuration to the outer radius of the stent 1 in its fully deployed configuration was calculated for stents 1 having differing numbers m of unit cells 3 in each row 8 of the sheet 2 around the tube. The relationship between R^* and m for Patterns 1, 2 and 3 is illustrated in Fig. 9 where Pattern 1 is shown by a continuous line, Pattern 2 is shown by a dotted line and Pattern 3 is shown by a dashed line.

10 For each model, it will be noted that the value of R^* decreases as the number m of unit cells 3 in each row 8 increases. In other words, a large value of m makes the pattern fold more compact in the radial direction. Thus the number m of unit cells 3 in each row 8 around the tube is preferably large to minimise the radius of the 15 stent 1 on collapse. However, increasing the number m of unit cells 3 in each row 8 causes the folding to become complex and potentially affected by the thickness of the material of the sheet 2. The number m of unit cells 3 in each row 8 should be selected to balance these two factors.

20 It will also be noted from Fig. 9 that as compared to Pattern 1, Pattern 2 has a lower value of R^* and hence folds more compactly, whereas Pattern 3 has a higher value of R^* and hence folds less compactly. However, the difference in the value of R^* between Patterns 1, 2 and 3 becomes small when m is larger than 9. When $m=10$ the radius of the stent 1 in its fully folded configuration is about 30% of that in its 25 fully deployed configuration, for each pattern.

Also, the value L^* of the ratio of the total length of the stent 1 in its fully folded configuration to the length of the stent 1 in its fully deployed configuration was calculated for different values of the number m of unit cells in each row 8 of the sheet 2 around the tube and for differing values of the number n of rows 8 along the 30 tube.

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Fig. 10 shows the value of L^* for each of Patterns 1 to 3 for differing values of n when $m=6$. In Fig. 10, Pattern 1 is shown by a continuous line, the Pattern 2 is shown by a dotted line and Pattern 3 is shown by a dashed line. It will be seen that for each model, the ratio L^* slowly decreases as n increases. This means that all three
5 Patterns fold more compactly in the longitudinal direction as the number n of rows 8 of unit cells 3 increases. The value of L^* becomes nearly constant when n is greater than 7, so there is no particular benefit in increasing the number n of unit cells 3 above about 7.

It will be noted that, as compared to Pattern 1 in the longitudinal direction,
10 Pattern 3 folds more compactly, whereas Pattern 2 folds less compactly but maintains flexibility. Therefore, pattern 3 is preferred for uses where longitudinal collapse is desirable to allow access of the stent 1 to the blocked site, whereas Pattern 2 is preferred for uses where the medical practitioner prefers the longitudinal collapse to be minimised.

15 Fig. 11 shows the value of L^* for Pattern 1 for different values of m when $n=7$. It will be noted that L^* becomes smaller as m increases. Thus increasing m reduces the longitudinal collapse of the stent 1 when folded, as well as reducing the radial collapse.

Figs. 12 and 13 are diagrams of the unit cells 3 of the Patterns 1-1 and 2-1
20 which are variations of Patterns 1 and 2, respectively. Fig. 14 is a diagram of Pattern 1-1 developed across the sheet 2. In both cases, the length of the unit cell 3 is increased so that the pairs of angular folds 7 intersect the central longitudinal fold 6 at separated positions O and X between which the central longitudinal fold 6 is a valley fold.

25 Figs. 15 to 19 are diagrams of the unit cell 3 of Patterns 1-2, 2-2, 3-1, 1-3 and 2-3, respectively, which are themselves variations of models 1, 2, 3, 1-1 and 2-1, respectively. Fig. 20 is a diagram of Pattern 1-2 with the unit cell 3 developed across the sheet of material 2. In each case, the variation is to provide an additional ring of valley folds 9. Each valley fold 9 extends parallel to an adjacent longitudinal
30 or transverse edge fold 4 or 5. The valley folds 9 extends between an angular fold 7

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and either another angular fold 7 or else the central longitudinal fold 6. The ring of valley folds 9 causes the surface of the unit cell 3 to be folded twice. Therefore inside the ring of valley folds 9, the folds of the basic unit cell 3, that is the angular fold 7 and the central longitudinal fold 6, reverse. That is to say, hill folds reverse to 5 valley folds and valley folds reverse to hill folds. Such a ring of valley folds 9 has the advantages that the double folding pattern causes the inner surface of the sheet 2 inside the tube to become smoother and allows the unit cell 3 to be folded more compactly, because the peak point O of the unit cell 3 in its folded state shown in Fig. 4 is folded inside points A and C of the folded unit cell 3, ie allowing the unit 10 cells 3 to be folded compactly in the radial direction.

The unit cells 3 described above are symmetrical both about the central longitudinal fold 6 and also about an imaginary line extending around the tube perpendicular to the central longitudinal fold 6. However, this is not essential. Either or both degrees of symmetry may be removed. For example Figs. 21 to 24 are 15 diagrams of Patterns 4-1 to 4-4, respectively, which are symmetrical only about the central longitudinal fold 6. Fig. 25 is a diagram of Pattern 4-1 with the unit cell 3 developed over the sheet 2. Accordingly, the unit cell 3 of alternate rows 8 is reversed in the longitudinal direction. This may also be viewed as a Pattern having a larger unit cell comprising the two unit cells 3 illustrated in Fig. 21 in bold outline 20 combined together. Patterns 4-1 to 4-4 may also be viewed as consisting of the other half of one of the Patterns described above with the lower of another of the Patterns described above. For example, Pattern 4-1 may be viewed as the upper half of Pattern 1 combined with the lower half of Pattern 2, and so on.

Figs. 26 to 29 are diagrams of the unit cell 3 of Patterns 5-1 to 5-4, 25 respectively, which are variations of Patterns 4-1 to 4-4, respectively, the variation is that the unit cell 3 further comprises a ring of valley folds 9 as in Patterns 1-2, 2-2, 3-1, 1-3 and 2-3.

Figs. 30 and 31 illustrate Patterns 6-1 and 6-2 which are symmetrical only about an imaginary line extending around the tube. These Patterns may also be 30 viewed as combinations of longitudinally-extending halves of different Patterns

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described above, except that the central longitudinal fold 6 extends at an angle to the longitudinal direction along which the longitudinal edge folds 4 extend. In particular, if the angle BAO is α_1 , and then the angle BCO is α_2 , then the angle AOB is α_2 , the angle BOC is α_1 , and both angles ABO and CBO are $(\pi - \alpha_1 - \alpha_2)$. For example,

- 5 Pattern 6-1 may be viewed as the combination of the left half of Pattern 1 with the right half of Pattern 2. Similarly, Pattern 6-2 may be viewed as the combination of the left half of Pattern 2-1 and the right half of Pattern 3.

Unlike the previous patterns, Pattern 6-2 cannot be used by itself, but must be combined with another pattern. For example, Fig. 32 is a diagram of Pattern 6-2 with
10 the unit cell 3 developed over a sheet 2 and combined with Pattern 3. To enable the unit cells to fit together, alternate unit cells 3 of Pattern 6-2 along each row 8 are longitudinally reversed and a unit cell of Pattern 3 is arranged between successive pairs of unit cells 3 of Pattern 6-2, between the longer longitudinal edges of the unit cells 3 of Pattern 6-2. Thus, a larger unit cell is formed by the combination of two
15 unit cells 3 of Pattern 6-2 with a unit cell of Pattern 3.

Figs. 33 and 34 are diagrams of the unit cell 3 of Patterns 7-1 and 7-2 which are variations of Patterns 6-1 and 6-2. The variation is the addition of a ring of valley folds 9 similar to the valley folds 9 of Patterns 1-2, 2-2, 3-1, 1-3 and 2-3.

In the Patterns described above, a single unit cell 3 is repeated over the entire
20 sheet, but this is not essential. In fact, different unit cells 3 may be repeated over different portions of the sheet 2. For example, Figs. 35 to 39 show patterns of folds in which different rows 8 comprise a respective, different unit cell 3 repeated around the tube. In Figs. 35 and 36, two different patterns are used. In Fig. 35, Patterns 1 and 1-1 are used for alternate rows. In Fig. 36, Patterns 1 and 1-2 are used for alternate
25 rows. In Figs. 37 and 38, three different patterns are used. In particular, in both Figs. 37 and 38 unit cells 3 of Patterns 1, 4-1 and 2 are used for different respective rows 8, although in a different order longitudinally along the tube.

Similarly, Fig. 39 is a diagram of a pattern of folds in which each row 8 comprises two different unit cells 3 alternating along the row 8, in particular the unit
30 cells of Patterns 1 and 1-2.

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The patterns of folds described above produce a tube which is generally cylindrical by means of the unit cells 3 being arranged with parallel longitudinal edge folds 4 and has the same radius along the length of the tube. However, this is not essential. For example, the sheet 2 may be arranged in a tube which is conical along 5 the entire length or along a portion thereof. This may be achieved using the pattern of folds illustrated in Fig. 40 which is based on a unit cell 3 of Pattern 2, but in which the unit cells 3 are of different sizes with the longitudinal edge folds 4 being angled relative to one another, instead of parallel. Therefore the longitudinal edge folds 4 are also angled with respect to the longitudinal direction of the tube. As a result, the sheet 10 2 of Fig. 40 forms a conical (or frustoconical) tube when folded. Alternatively, the tube may have a more complicated structure, for example having plural tubular portions branching off from a common node.

Figs. 41 and 42 are diagrams of patterns in which unit cells 3 are arranged on the sheet 2 in rows 8 which progress helically around the tube when the sheet 2 is 15 folded. Figs. 41 and 42 are based on a unit cell of Pattern 1, but any of the patterns described above could alternatively be used. Consequently, the rows 8 of unit cells are arranged at a pitch angle or helix angle β which is the angle between the direction in which the unit cells repeat and plane perpendicular to the longitudinal axis of the tube. When the sheet 2 is folded with the opposite lines a-a and b-b in Fig 41 and 42 20 being the same line, successive rows 8 of unit cells 3 join end-to-end to form a longer row which progresses helically around the tube. In the pattern of Fig. 41, the angle α is selected so that the rows 8 combine to form a single row progressing helically around the tube. In the pattern of Fig. 42, the angle β is selected so that the rows 8 join together to form two rows progressing helically around the tube.

25 As a result of the helical pattern it will also be noted that the longitudinal edge folds 4 and the central longitudinal folds 6 of alternate rows 8 meet together to form an uninterrupted fold line which also progresses helically around the tube.

Such a helical structure provides a number of advantages. Firstly, it allows the sheet 2 to be folded compactly in the longitudinal direction because of its capability of 30 torsion. Secondly, the helical pattern assists with deployment, because the expansion

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and collapse of the sheet 2 is usually synchronised over the area of the sheet 2. That is to say, the helical progression of the pattern of folds spreads the force causing expansion or collapse to be transmitted along the length of the tube. This may be viewed as the force being transmitted along the uninterrupted lines of folds formed by

5 the longitudinal edge folds 4 and the central longitudinal folds 6 of alternate rows 2 which progress helically around the tube. This means that a twist applied to the stent 1 can be used to generate expansion or collapse of the stent 1 which greatly assists deployment because a twist is simple to perform. Thirdly, the helical structure holds the stent 1 in its expanded configuration. This is because collapse of the stent requires

10 torsional forces which are not usually developed at sites in the body.

The patterns described above are preferred because of their simplicity and hence ease of design and manufacture. However a stent in accordance with the present invention may be formed using numerous other patterns of folds which allow radial collapse and optionally longitudinal collapse. Alternative patterns may be

15 regular or irregular and the sheet between the folds may in general be flat or curved.

The stents described above may be combined together to form a larger product or may have additional components added thereto.

Manufacture of a stent 1 in accordance with the present invention will now be described.

20 First, the biocompatible sheet 2 is provided.

The sheet may initially be planar, in which case opposed edges of the sheet are subsequently joined together to form a tube. In this case, in the drawings, the lines a-a and b-b may represent edges of the sheet 2 which are joined together. Alternatively, the sheet 2 may be manufactured be formed as a tube ab initio, that is with the sheet

25 being continuous around the tube. In this case, in the drawing, the lines a-a and b-b are the same imaginary line along the length of the tube. This latter alternative has the advantage of avoiding the need to join the edges of a planar sheet but makes it harder to form the folds.

In its most simple form, the sheet 2 is a sheet of biocompatible material. Any

30 biocompatible material may be used. Generally, a biocompatible material is selected

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with appropriate mechanical properties for the site at which the stent 1 is to be used. The material should be selected to be sufficiently rigid to hold its shape between the folds when implanted in a lumen. This is to perform its basic function of holding the lumen open. This must be balanced against the ease of folding the sheet and the need
5 for the collapsed stent 1 to be sufficiently flexible to allow delivery to the blocked site.

Suitable materials for the sheet 2 include stainless steel or a shape memory alloy such as Nitinol. It is also anticipated that many polymers would be suitable.

The sheet 2 is desirably selected so that the outer surface of the sheet 2 on the
10 outside of the tube provides a sufficient degree of friction to provide anchorage at the anatomical site where it is to be implanted. This may be achieved by selecting a material providing an appropriate degree of friction or by roughening the outer surface.

Alternatively, the sheet 2 may be a multi-layer material. In that case, the inner
15 and outer layers may be selected to provide appropriate degrees of friction. Desirably the outer surface of the sheet 2 on the outside of the tube provides a higher degree of friction than the inner surface of the sheet 2 of the inner side of the tube.

In another form, the sheet 2 may have a coating of a biocompatible material.

The sheet 2 is folded with the desired pattern of folds. This may be achieved
20 by initially forming fold lines which facilitate subsequent folding. For example, the fold lines may be formed by scoring the sheet or by stamping the sheet from both sides by stamps having ridges along the fold lines, the stamp on one side having the pattern of hill folds the other side having the pattern of valley folds.

However the preferred techniques to form fold lines are laser lithography and
25 chemical etching.

In the case of laser lithography, a laser is used to form scores in the surface of the sheet 2 along the fold lines. The laser equipment for such processing is in itself conventional.

In the case of chemical etching, the sheet 2 is first masked by a material
30 resistant to a chemical enchanter, except along the desired pattern of folds. Then the

-16-

etchant is applied to the sheet to etch scores in the pattern of folds where the masking material is not present. Subsequently the masking material is removed. Such a chemical etching process in itself is conventional. Preferably, a conventional photolithographic technique is used. In such a case, the masking material is a positive or negative photoresist applied across the entire sheet. Ultra-violet light is applied in an image of the pattern of folds, being positive or negative image for the case of a positive or negative photoresist, respectively. This alters the photoresist allowing it to be removed by the etchant in the pattern of folds, but leaving it resistant to the etchant elsewhere.

10 In general, the etchant and the masking material may be chosen having regard to the material of the sheet 2. However, particular possibilities are as follows.

In the case of a chemical etching of a sheet 2 of stainless steel, one possibility is to use the negative etching technique commonly used for etching stainless steel, for example using ferric chloride and 1% HCl as the etchant and using a dry film as a negative photoresist.

15 In the case of chemical etching of a sheet 2 of shape memory alloy, the following positive etching technique has been applied using a positive photoresist layer of solid contented HRP 504 or 506 as the masking material and using a mixture of hydrofluoric and nitric acid as the etchant. The etching method was applied to a sheet 2 of thickness 80 μ m and size 80mm x 80mm which was cleaned to improve the adhesion of the masking material. The masking material was applied by dip coating at a speed of 6mm/min to create a coating of thickness 12 μ m. The sheet 2 was then soft-baked at 75° for 30 minutes. The masking material was then exposed by UV light with a positive image of the pattern of folds on both sides of the sheet, and the image developed using PLS1: H₂O = 1:4. Finally the sheet 2 was hard-baked at 120° for 60 minutes. The sheet 2 was then etched using a mixture of hydrofluoric acid and nitric acid in proportions HF 10%, HNO₃ 40%, H₂O 50% or HF:HNO₃:H₂O = 1:1:2 or 1:1:4.

20 Other ways to chemically etch a sheet 2 of shape memory alloy are negative etching with a rubber-type of photoresist or electrochemical etching with
25 H₂SO₄/CH₃OH, for example as disclosed in Eiji Makino, et al., "Electrochemical

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Photoetching of Rolled Shape Memory Alloy Sheets for Microactuators", Vol. 49, No. 8, 1998; and D M Allen, "The Principles and Practice of Photochemical Machining and Photoetching", Adam Hilger, 1986.

In the case of a sheet 2 which is initially planar, after folding the edges of the
5 folded sheet 2 are joined together to form the sheet 2 into a tube.

As the stent is folded from a sheet 2, it is possible to manufacture it relatively cheaply. It is anticipated that manufacturing costs may be kept below current costs of many existing expandable stents.

The dimensions of the sheet 2, the type of pattern of folds and the dimensions
10 of the unit cell 3 within the pattern of folds are selected based on the site at which the stent is intended to be used. The stent 1 may be used for treatment at sites in any type of lumen in the body simply by choice the dimensions and mechanical properties of the sheet of the stent 1. Once deployed, the stent 1 prevents restenosis, because it is formed from a sheet 2 which is effectively continuous. The stent 1 is particularly
15 advantageous for use in the oesophagus where restenosis is a particular problem.

The stent 1 is used in the same manner as known stents, that is by initially collapsing the stent 1 to deliver the stent 1 to the site to be treated and subsequently expanding the stent 1. Manipulation of the stent 1 is performed using conventional medical techniques.

20 A potential problem with the stent 1 as described above is that high stresses are developed at the nodes where the folds 4 to 7 intersect. Such stresses could create weakness at the nodes, potentially causing sheet 2 to puncture or rip. To avoid this problem, aperture 10 may be formed in the sheet 2 at the nodes where the folds 4 and 7 intersect, or at least at those nodes where high stresses are likely to be developed.

25 An example of such an aperture 10 formed in a sheet 2 at the node where the longitudinal edge folds 4, the transverse edge folds 5 and the angular fold 7 intersect is shown in Fig. 43. The aperture 10 in Fig. 43 is shown as being circular, but may be of any shape. The aperture 10 is sufficiently small that it does not allow significant ingrowth through the aperture 10, hence effectively retaining the continuous nature of
30 the sheet 2.

CLAIMS

1. A stent comprising a biocompatible sheet arranged as a tube folded with a pattern of folds allowing the stent to be collapsed for deployment.

5

2. A stent according to claim 1, wherein the pattern of folds comprises a unit cell repeated over at least a portion of the sheet.

3. A stent according to claim 2, wherein the unit cell comprises:

10 an outer circumferential edge of folds of a first type comprising a pair of longitudinal edge folds extending along the tube and transverse edge folds extending around the tube;

a central longitudinal fold extending along the tube between the transverse edge folds; and

15 angular folds extending from each intersection of a longitudinal edge fold with a transverse edge fold to the central longitudinal fold.

4. A stent according to claim 3, wherein for each pair of angular folds at opposite longitudinal ends of the unit cell, the pair of angular folds intersect the central

20 longitudinal fold at the same position.

5. A stent according to claim 4, wherein the lengths of :

a transverse edge fold from the intersection with a longitudinal edge fold to a central intersection with the central longitudinal fold; and

25 the portion of the central longitudinal fold from said central intersection with the transverse edge fold to the intersection with the angular folds,

are the same.

6. A stent according to any one of claims 3 to 5, wherein the angular folds are

30 folds of a second type inverse to said first type and the portions of the central

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longitudinal fold extending from a respective one of the transverse edge folds to a respective intersection with the angular folds are folds of said first type.

7. A stent according to any one of claims 3 to 6, wherein the angular folds all
5 intersect the central longitudinal fold at the same position

8. A stent according to any one of claims 3 to 6, wherein said pairs of angular folds intersect the central longitudinal fold at separated positions between which the central longitudinal fold is a fold of said second type.

10

9. A stent according to any one of claims 3 to 8, wherein the angle between a transverse edge fold and an angular fold is 45° .

10. A stent according to any one of claims 3 to 8, wherein the angle between a
15 transverse edge fold and an angular fold is less than 45° .

11. A stent according to any one of claims 3 to 8, wherein the angle between a transverse edge fold and an angular fold is greater than 45° and less than or equal to
60°.

20

12. A stent according to any one of claims 3 to 11, wherein the unit cell further comprises a ring of folds of said second type each parallel to an adjacent edge fold, the pattern of folds inside the ring of folds of said second type reversing from folds of said first type to folds of said second type and vice versa.

25

13. A stent according to any one of claims 3 to 12, wherein the unit cell is symmetrical about the central longitudinal fold.

14. A stent according to any one of claims 3 to 13, wherein the unit cell is
30 symmetrical about an imaginary line extending around the tube.

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15. A stent according to any one of claims 3 to 13, wherein the folds of said first type are hill folds and the folds of said second type are valley folds.
16. A stent according to any one of claims 2 to 15, wherein the pattern of folds comprises a single unit cell repeated over the entire sheet.
17. A stent according to any one of claims 2 to 16, wherein the pattern of folds comprises a plurality of rows of unit cells extending around the tube.
- 10 18. A stent according to claim 17 when appendant to claim 3, wherein the unit cells of adjacent rows are offset with the longitudinal edge folds of each row meeting the central longitudinal folds of the adjacent rows.
- 15 19. A stent according to claim 18, wherein the longitudinal edge folds of alternate rows and the central longitudinal folds which meet form an uninterrupted fold line progressing helically around the tube.
- 20 20. A stent according to any one of claims 17 to 19, wherein at least two of the rows comprise a respective, different unit cell repeated around the tube.
- 20 21. A stent according to any one of claims 2 to 15, wherein the pattern of folds comprises at least one row of unit cells progressing helically around the tube.
- 25 22. A stent according to claim 22, wherein the pattern of folds comprises two rows of unit cells each two rows progressing helically around the tube.
23. A stent according to any one of the preceding claims, wherein the pattern of folds includes uninterrupted lines of folds progressing helically around the tube.
- 30 24. A stent according to any one of the preceding claims, wherein the tube is

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conical along at least a portion thereof.

25. A stent according to any one of the preceding claims, wherein the sheet has apertures at at least some of the nodes where folds intersect.

5

26. A stent according to any one of the preceding claims, wherein the outer surface of the sheet on the outer side of the tube has a higher degree of friction than the inner surface of the sheet on the inner side of the tube.

10 27. A stent according to any one of the preceding claims, wherein the outer surface of the sheet on the outer side of the tube is roughened.

15 28. A stent according to any one of the preceding claims wherein the outer surface of the sheet on the outer side of the tube has a sufficient degree of friction to provide anchorage at an anatomical site.

29. A stent according to any one of the preceding claims, wherein the sheet has edges joined along the length of the tube.

20 30. A stent according to any one of claims 1 to 28, wherein the sheet is continuous around the tube.

31. Use of a stent according to any one of the preceding claims.

25 32. A planar sheet of biocompatible material having a pattern of fold lines arranged to allow the sheet to be folded into a tube to form a stent which is collapsible for deployment.

30 33. A method of manufacturing a stent comprising folding a planar sheet of biocompatible material into a tube with a pattern of folds allowing the stent to be

-22-

collapsed for deployment.

34. A method of manufacturing a stent comprising folding a sheet of biocompatible material in the form of a tube with a pattern of folds allowing the stent to be collapsed
5 for deployment.

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Fig.1.

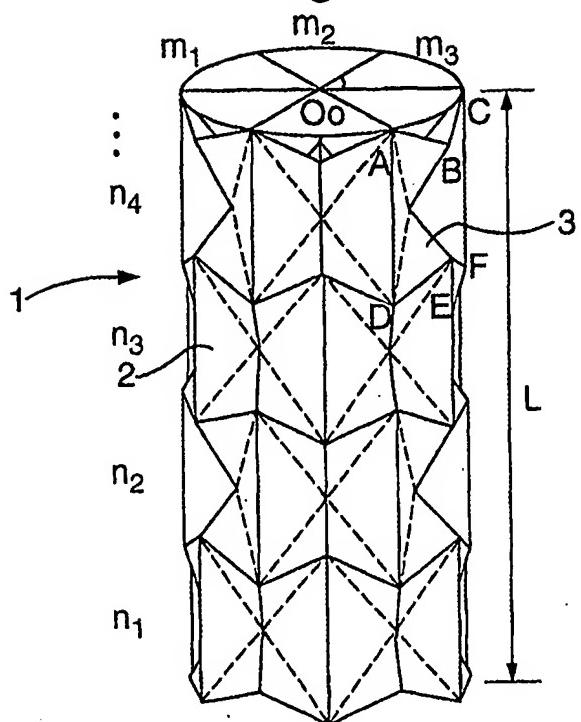


Fig.2.

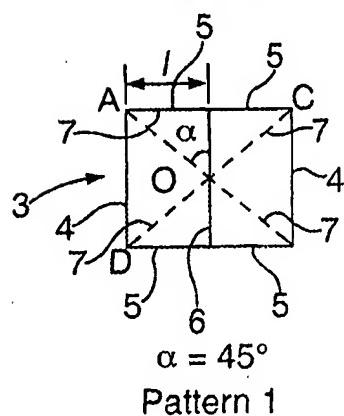


Fig.3.

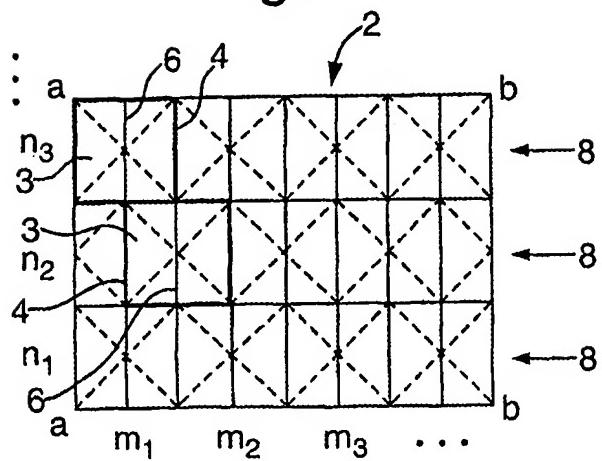
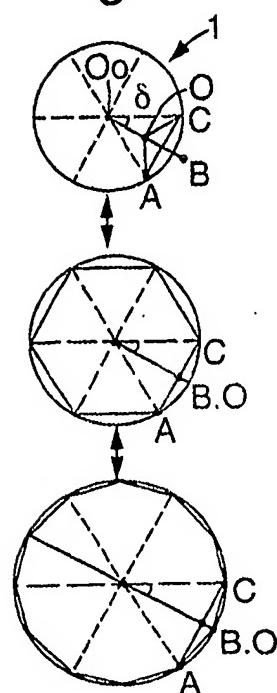


Fig.4.



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Fig.5.

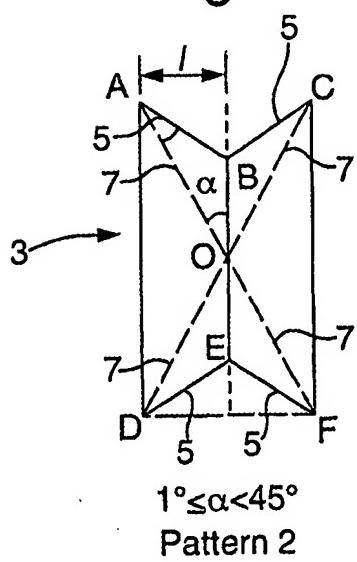


Fig. 6.

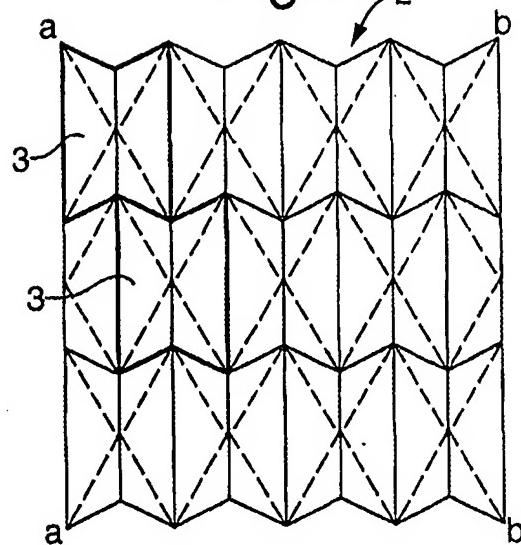


Fig.7.

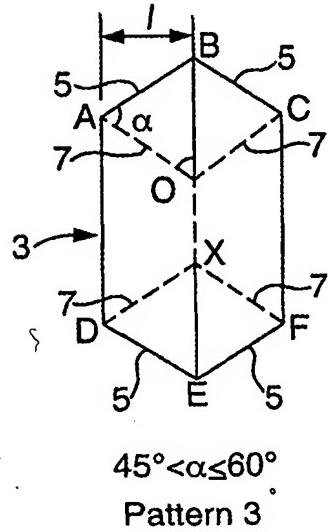
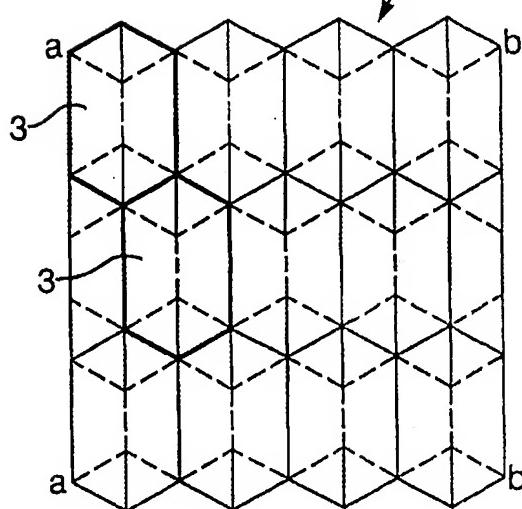
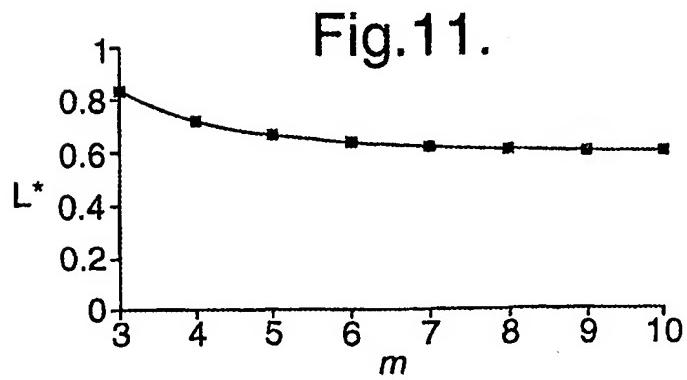
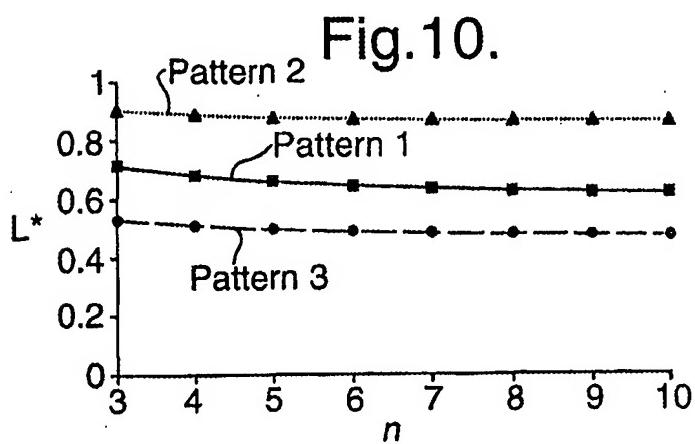
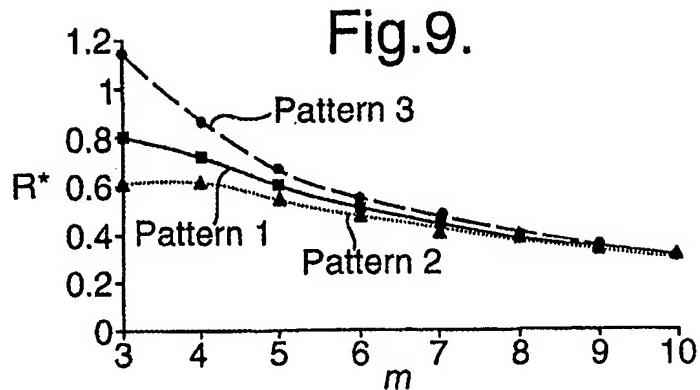


Fig.8.

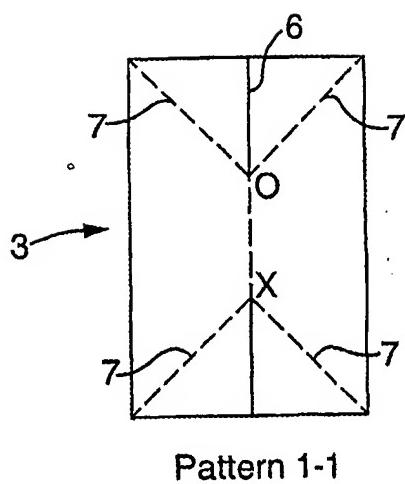


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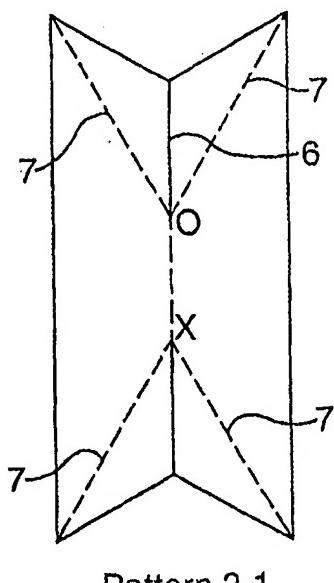
4/12

Fig.12.



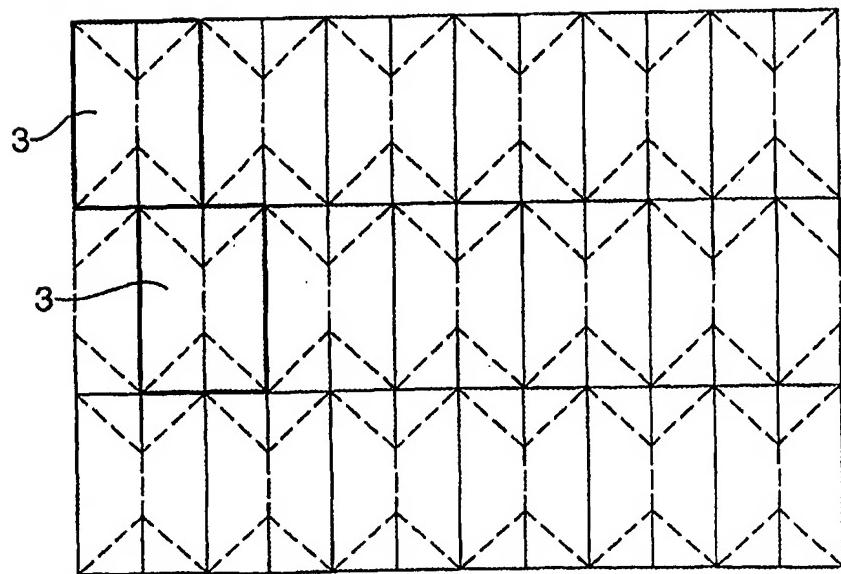
Pattern 1-1

Fig.13.

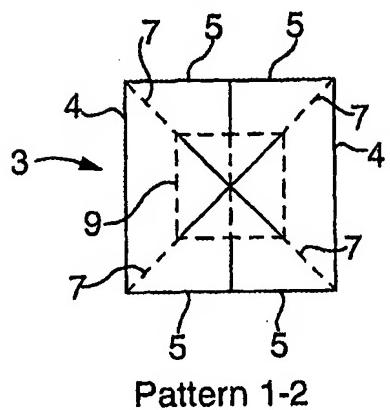
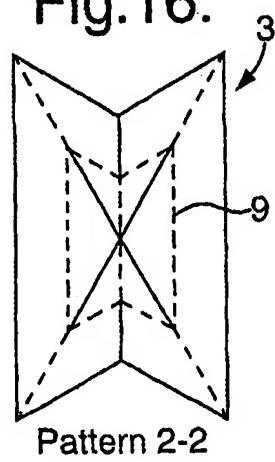
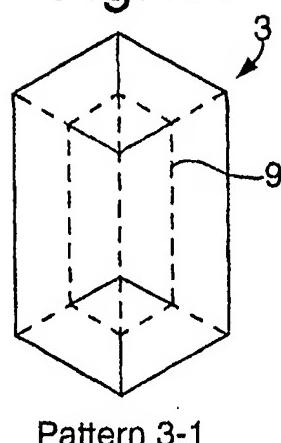
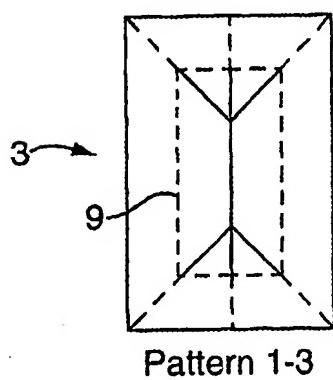
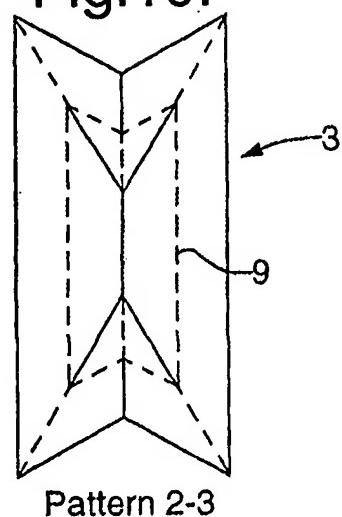
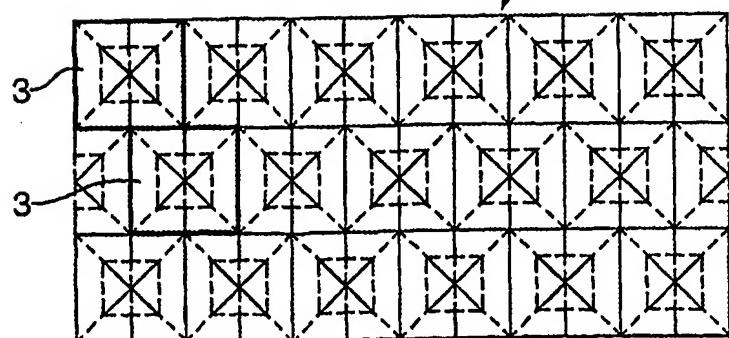


Pattern 2-1

Fig.14.

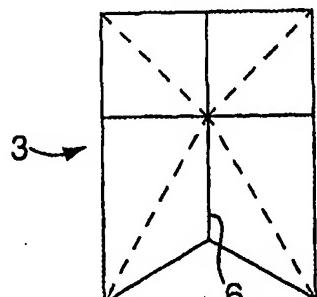


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Fig.15.**Fig.16.****Fig.17.****Fig.18.****Fig.19.****Fig.20.**

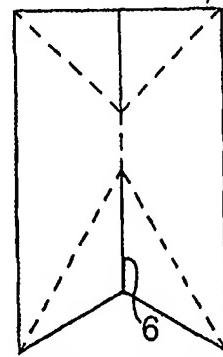
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Fig.21.



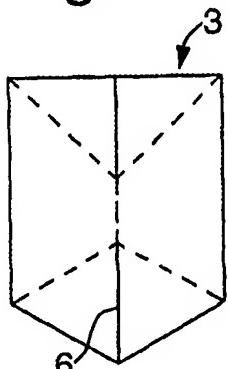
Pattern 4-1

Fig.22.



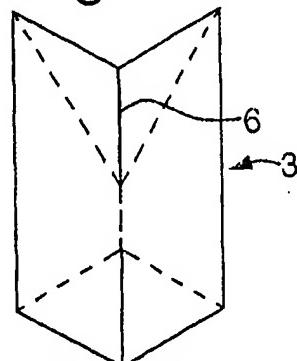
Pattern 4-2

Fig.23.

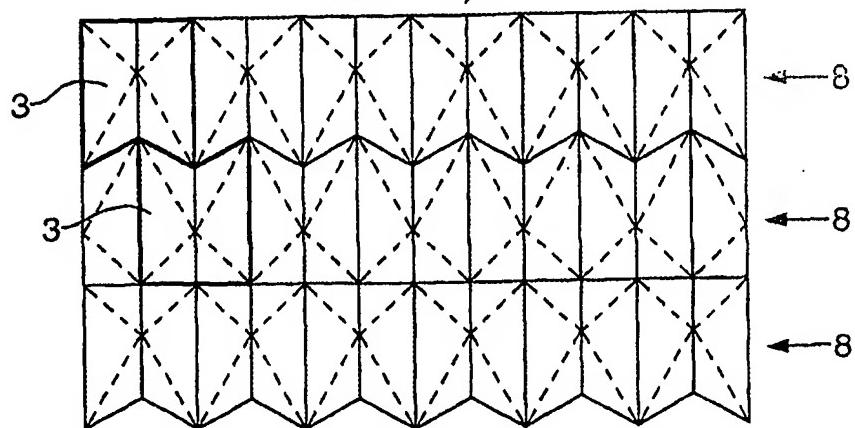


Pattern 4-3

Fig.24.

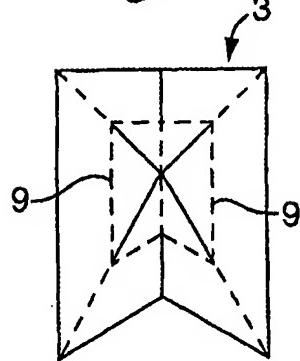


Pattern 4-4

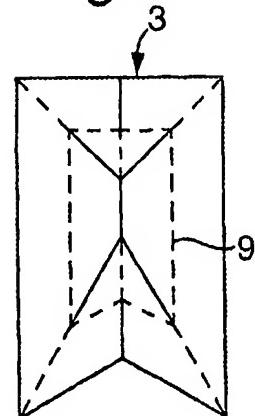
Fig.25.²

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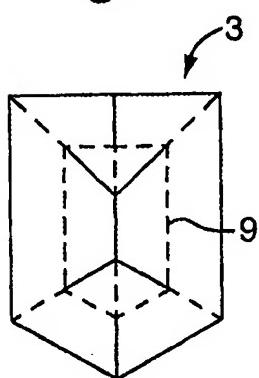
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Fig.26.

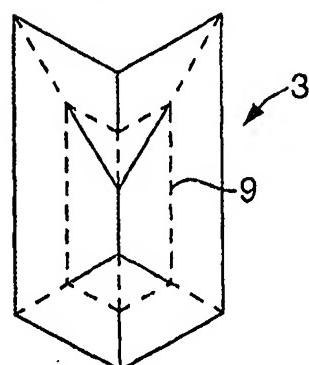
Pattern 5-1

Fig.27.

Pattern 5-2

Fig.28.

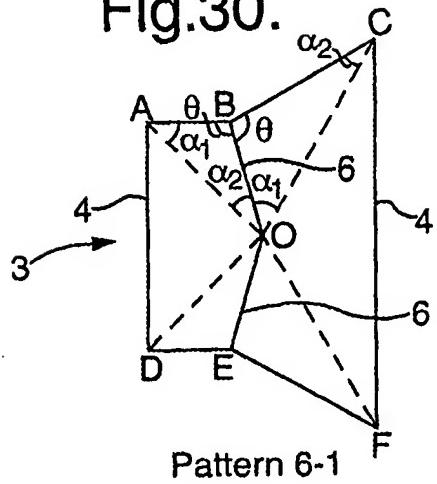
Pattern 5-3

Fig.29.

Pattern 5-4

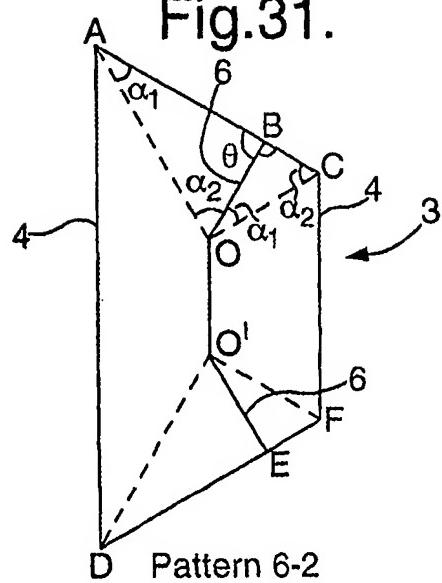
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Fig.30.



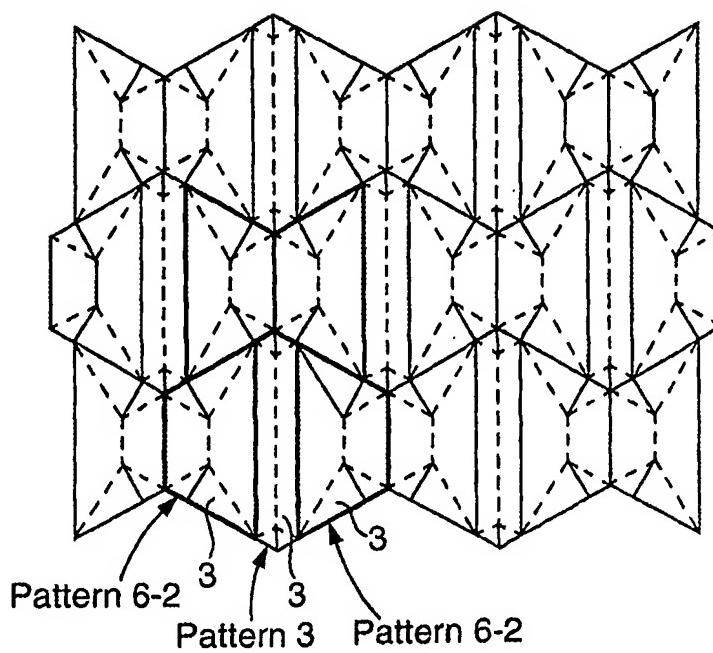
Pattern 6-1

Fig.31.



Pattern 6-2

Fig.32.



Pattern 6-2

3

3

Pattern 6-2

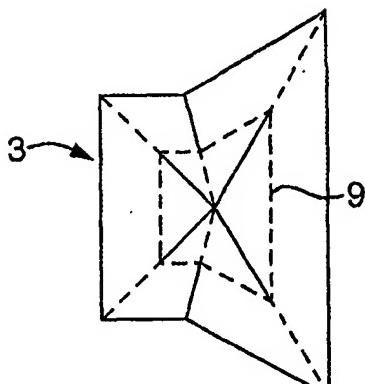
3

3

Pattern 3

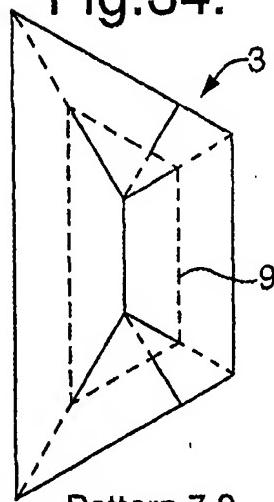
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Fig.33.



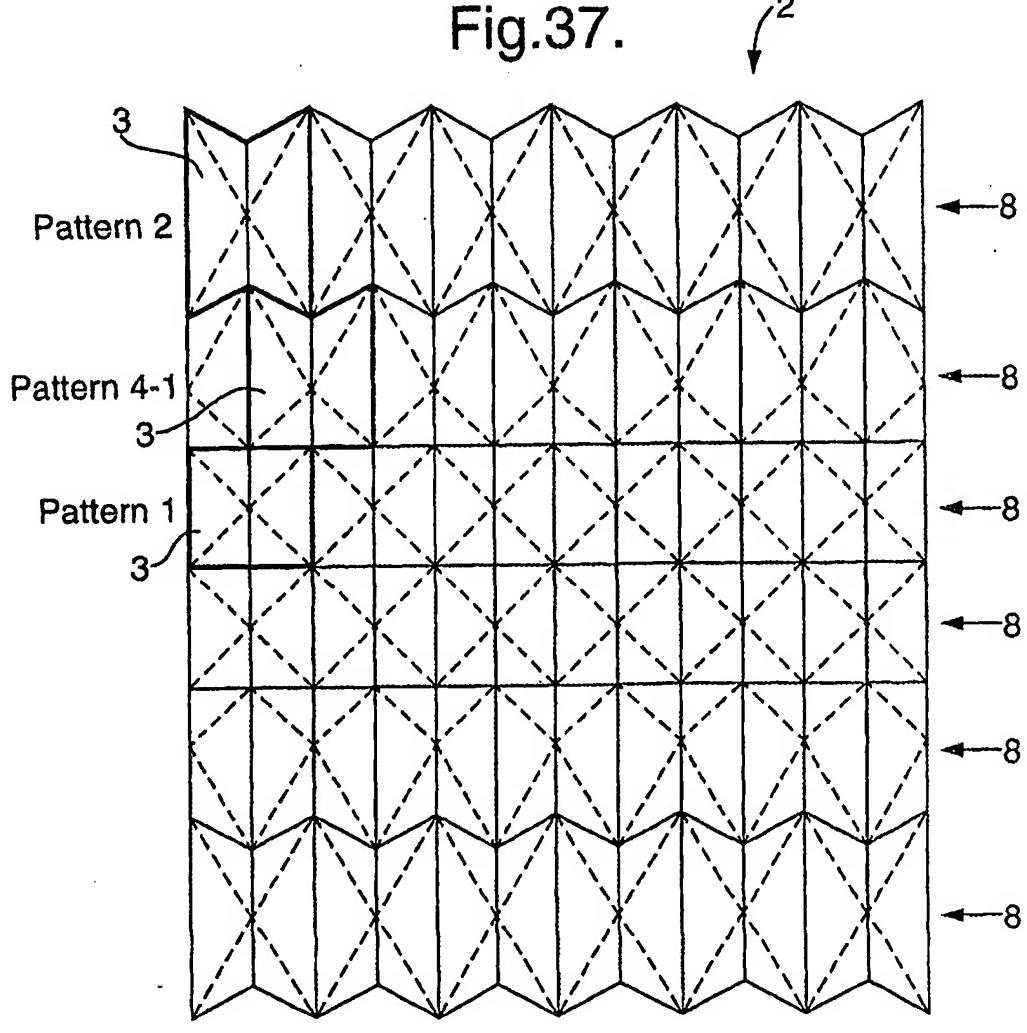
Pattern 7-1

Fig.34.



Pattern 7-2

Fig.37.



SUBSTITUTE SHEET (RULE 26)

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Fig.35.

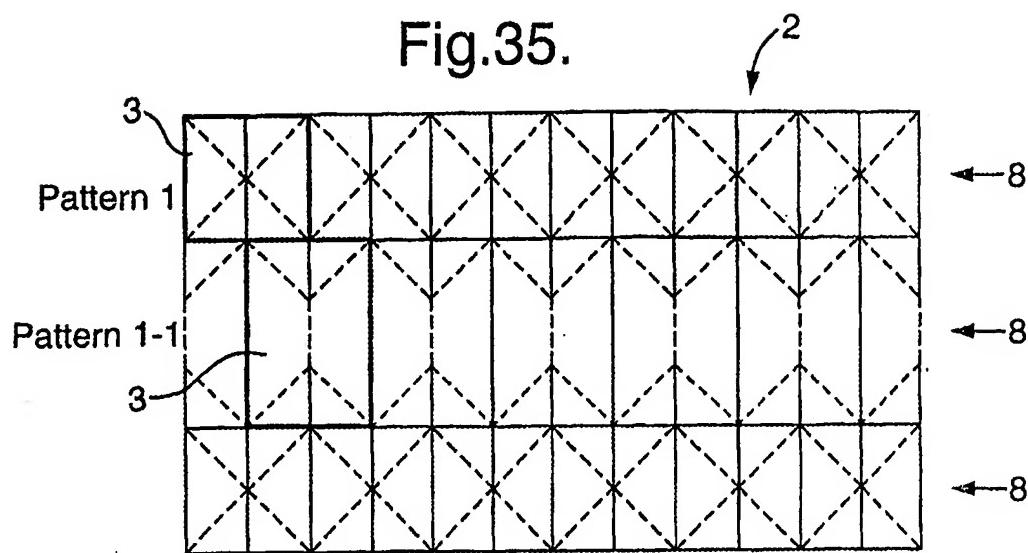


Fig.36.

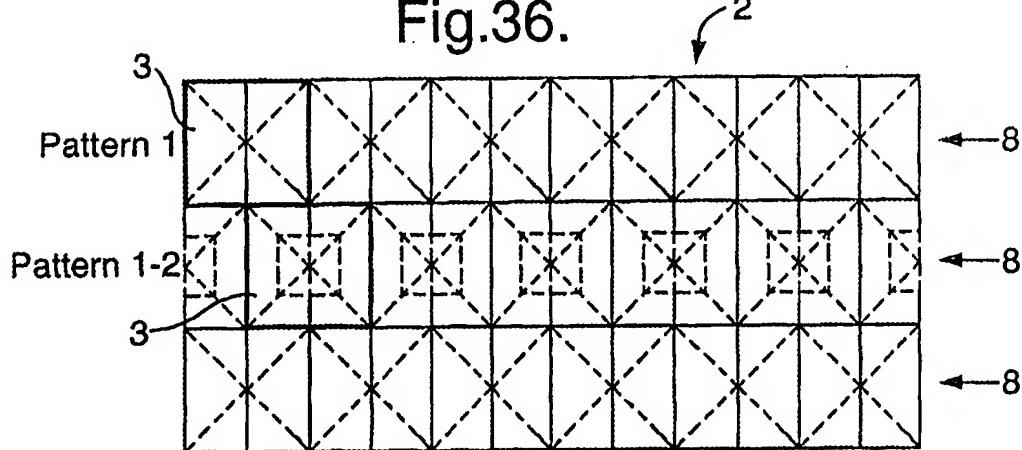
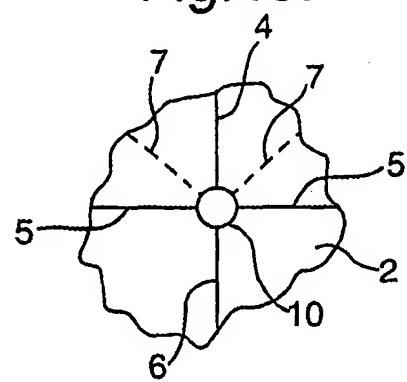


Fig.43.



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Fig.38.

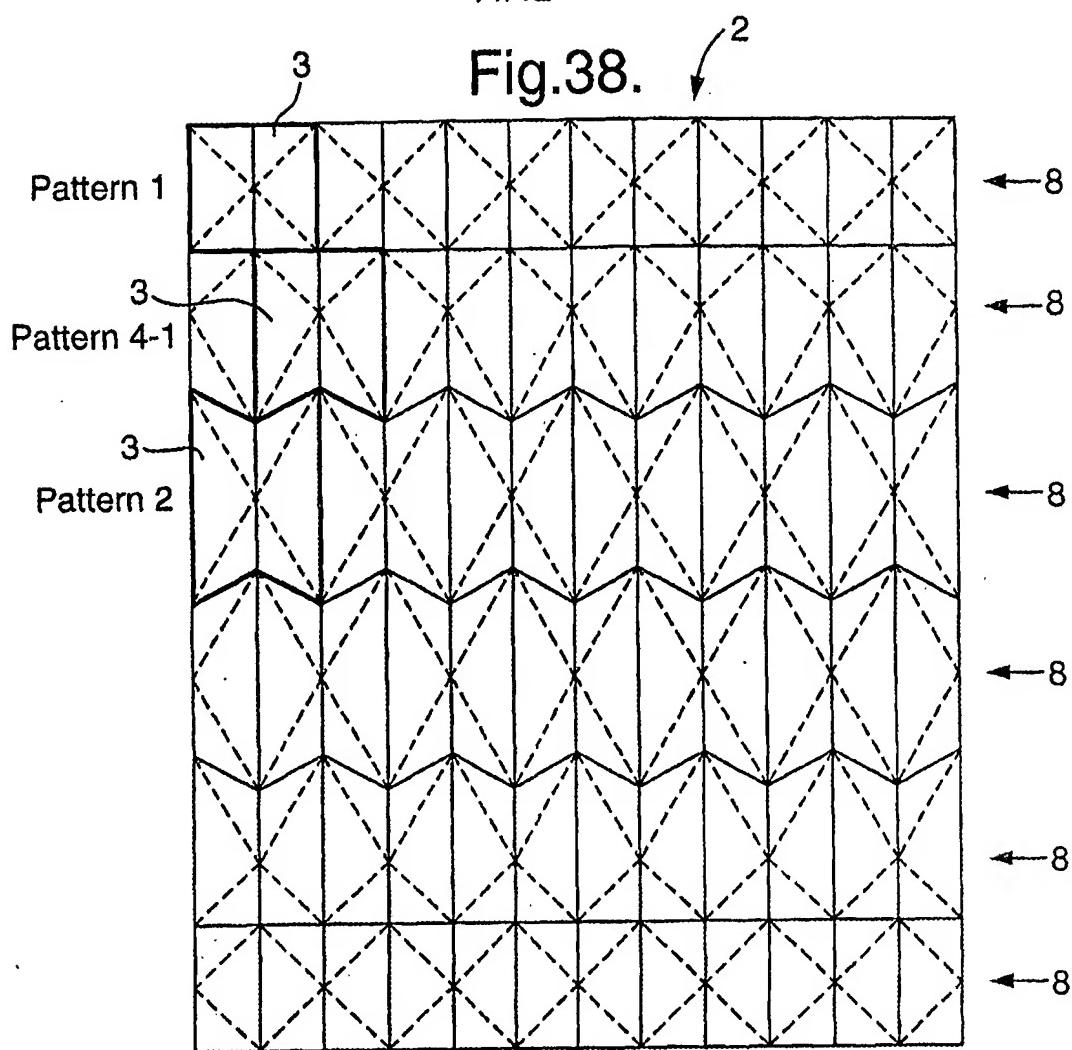
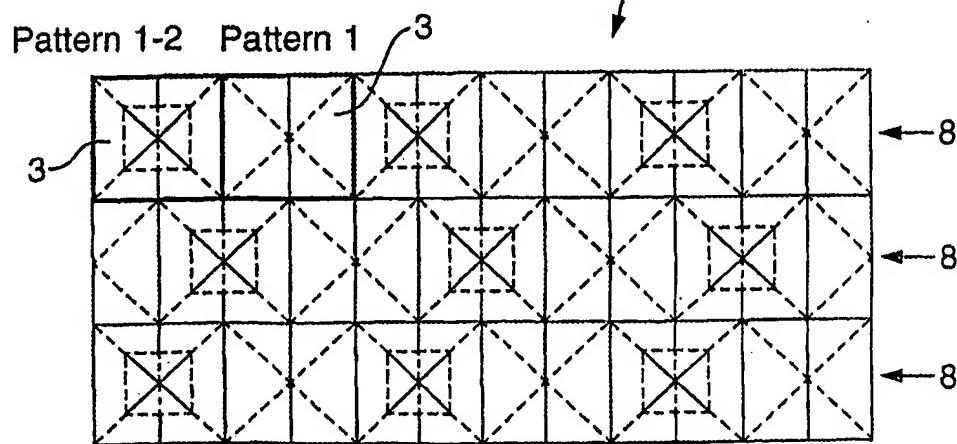


Fig.39.



INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 02/01424

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 653 745 A (LINDELL ELAINE ET AL) 5 August 1997 (1997-08-05) claims; figures ---	1,23, 32-34
X	US 5 507 770 A (TURK RODNEY E) 16 April 1996 (1996-04-16) abstract; figures 1,2 ---	1,32-34
A	US 5 855 597 A (JAYARAMAN SWAMINATHAN) 5 January 1999 (1999-01-05) column 1, line 26 – line 49; figures ---	1,32-34
A	US 5 735 871 A (SGRO JEAN-CLAUDE) 7 April 1998 (1998-04-07) figures ---	1,33,34 -/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents:

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- *L* document which may throw doubts on priority, claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Z document member of the same patent family

Date of the actual completion of the International search

Date of mailing of the International search report

5 June 2002

21/06/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Neumann, E

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 02/01424

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95 13033 A (LAZARUS HARRISON M) 18 May 1995 (1995-05-18) claims; figures	1

INTERNATIONAL SEARCH REPORT

national application No.
PCT/GB 02/01424

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 31 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 02/01424

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 5653745	A	05-08-1997	US	5607464 A	04-03-1997
			US	5282847 A	01-02-1994
US 5507770	A	16-04-1996	AU	686039 B2	29-01-1998
			AU	4411296 A	17-06-1996
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